EXPANDABLE BLOOD PUMP AND RELATED METHODS

CROSS-REFERENCES TO RELATED APPLICATIONS

The present application is an International Patent Application of and claims the benefit of priority from commonly owned and co-pending U.S. Provisional Patent Applications Serial Nos. 60/388,136 (filed June 11, 2002), the entire contents of which is hereby expressly incorporated by reference into this disclosure as if set forth fully herein.

BACKGROUND OF THE INVENTION

I. Field of the Invention

The present invention relates generally to a system for assisting the heart and, more particularly, to a pumping system and related method for supplementing the circulation of blood through the patient using a minimally invasive procedure.

II. Description of Related Art

Over the years, various types of percutaneously introduced blood pumps have been developed for the purpose of augmenting or replacing the blood pumping action of damaged or diseased hearts. Such blood pumps may be positioned within the heart of the patient (so-called "intracardiac blood pumps") or may be positioned within the associated vasculature of the patient (so-called "intravascular blood pumps"). Such percutaneously introduced blood pumps have experienced proliferated growth and attention in that they are capable of supplementing or replacing the circulation of blood through the patient using minimally invasive techniques (eliminating the trauma of an open procedure), and minimize the need to route the blood outside the patient (reducing trauma to the blood).

Although generally advantageous for these reasons, among others, the percutaneously introduced blood pumps of the prior art nonetheless suffer from various drawbacks. One such drawback involves the tradeoff between the size of the pump and the ability to deliver blood at sufficient rates. For example, the Hemopump is an axial flow blood pump which meets the criteria for blood flow (approximately 3 liters per minute) but it is too large (14 to 22 French) for easy insertion by a cardiologist. Although smaller versions of the Hemopump could be built, physics limits the flow because as the

pump becomes smaller, the inlet area decreases. Losses in the pump increase in a rapid, non-linear manner as the inlet area decreases. To compensate for these rapidly increasing losses, the rotor speed must be increased exponentially. Although adequate flow may be achieved, hemolysis increases to unacceptable levels.

Thus the engineer faces theoretical and technical difficulties to make a traditional propeller pump or centrifugal pump with the diameter less than 4.0 mm and a flow of at least 3 liters per minute. One way to circumvent the physical limitations imposed by a decreasing inlet area is to make the pump expandable. In this way, inlet losses and shaft speed can be minimized since large areas can be achieved after the pump is inserted. Cable driven axial flow blood pumps have been described which use a hinged propeller that deploys after insertion into the arterial system. However, the work delivered by the hinged rotor was not constrained by a housing to create an effective blood pumping from inlet to outlet. Rather, these pumps have created a significant blood re-circulation without much effective blood pumping.

The present invention is directed at eliminating, or at least reducing the effects of, the above-described problems with the prior art.

SUMMARY OF THE INVENTION

The present invention overcomes the limitations of the prior art by providing a pumping system capable of being expanded from a first state of generally reduced dimension to a second state of generally increased dimension. The blood pump of the present invention may be advantageously introduced into the patient (and onward to the pumping site) while in the first state and thereafter operated (automatically or manually) into the second state for use in pumping blood to augment or replace the pumping capacity of the patient's heart. More specifically, this is accomplished by equipping the blood pump of the present invention with a pump housing with an internally disposed rotor, wherein each of the pump housing and rotor are capable of being expanded from a first state of generally reduced dimension to a second state of generally increased dimension. In this fashion, the blood pump of the present invention may be percutaneously introduced through a much smaller opening than prior art blood pumps without sacrificing the degree to which it can achieve high blood flow rates.

The present invention also achieves a variety of objectives, several of which are set forth below by way of example only. One such objective is to achieve the benefits of an expandable pump by using a centrifugal rotor in association with a housing designed to channel blood away from the rotor in order to increase the pump efficiency.

It is another object of the present invention to provide a blood pump, which is expandable to allow device insertion through a peripheral vessel without the need of a surgical access.

A further object of the invention is to provide a blood pump with a small diameter that is small enough to permit percutaneous insertion of the pump into a patient's blood vessel.

It is another object of the present invention to provide a blood pump, which is expandable to allow the increased flow capacity of a small diameter pump.

In the illustrative embodiment of the present invention, the blood pump head has a conical housing portion. The conical housing portion defines a blood inlet port, a cavity for rotor deployment, and an outflow port, which is in communication with an outflow cannula.

In the illustrative embodiment, the housing is supported by the deploying catheter to maintain a cylindrical shape and assure the separation between the rotor and housing.

In one embodiment, the impeller comprises a second expandable catheter, wherein upon expansion forms the blade of the impeller.

In another embodiment, the impeller comprises multiple discs that are inserted in the folded position and naturally deploy to a circular shape when are not constrained.

In another embodiment, the impeller is formed by a slit tube that deforms to form a conical shape when the distal and proximal ends are pulled toward each other. A soft thin sheath covering the slit tube will deform to form the outer skin of the conical shape. In essence, the outer sheath could deform to form ridges simulating an impeller shape.

In the illustrative embodiment, the impeller shaft is magnetically coupled to the motor. In another embodiment, the motor is coupled to the impeller shaft via a flexible shaft.

In one embodiment, the blood pump has an outer dimension that is small enough to permit percutaneous insertion of the pump into a patient's blood vessel. A collapsible polymeric outflow tube is provided and is coupled to the blood flow outlet of the pump and is adapted for directing the blood from the left ventricle of the patient to the aorta through the aortic valve.

In accordance with the present invention, a method is provided for pumping blood. The method comprises the steps of providing an expandable pump head having an elongated housing portion defining a blood inlet port on a surface thereof and a blood outlet port on a surface thereof; providing an impeller within said housing portion for providing centrifugal or axial flow of the blood from the inlet port to the outlet port; and driving the expandable pump head with a motor to rotate the impeller and accelerate the blood from the inlet port within the housing portion.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1a is a schematic illustration of the frontal view of the pump head in the expanded status according to the present invention;

FIG. 1b is a schematic illustration of the side view of the pump head in the expanded status;

FIG 2a is a schematic illustration of the frontal view of the pump head in the collapsed status;

FIG. 2b 1a is a schematic illustration of the side view of the pump head in the collapsed status;

FIG. 3a is a longitudinal cross-sectional view of the pump head in the expanded status;

FIG. 3b is a longitudinal cross-sectional view of the pump head in the collapsed status;

FIG. 3c is a schematic illustration of the frontal view of the pump head in the expanded status;

FIG. 3d is a schematic illustration of the frontal view of the pump head in the collapsed status;

FIG. 4a is a longitudinal cross-sectional view of the pump head in the expanded status;

FIG. 4b is a radial cross-sectional view along line A—A of FIG 4a showing the pump head in the expanded status;

FIG 5a is an enlarged view of the circled section of the longitudinal cross-sectional view of the pump head in the expanded status with details to blood seal and pump bearings;

FIG 5b is an enlarged view of the circled section of the longitudinal cross-sectional view of the pump head in the collapsed status with details to blood seal and pump bearings;

FIG 6 is a schematic illustration of the side view of the outflow cannula in the expanded status;

FIG 7a is a schematic illustration of the frontal view of an alternative embodiment of the pump rotor in the collapsed status according to the present invention;

FIG 7b is a schematic illustration of the frontal view of the alternative embodiment shown in FIG 7a of the pump rotor in the expanded status according to the present invention;

FIG. 8a is a longitudinal cross-sectional view an alternative embodiment of the pump head and outflow cannula in the expanded status according to the present invention;

FIG 8b is a schematic illustration of the frontal view the alternative embodiment shown in FIG 8a of the pump head and outflow cannula in the expanded status;

FIG. 8c is a longitudinal cross-sectional view the alternative embodiment shown in FIG 8a of the pump head and outflow cannula in the collapsed status according to the present invention;

FIG 8d is a schematic illustration of the frontal view the alternative embodiment shown in FIG 8a of the pump head and outflow cannula in the collapsed status according to the present invention;

FIG 9 is a schematic illustration of the side view of an alternative embodiment of the pump rotor in the expanded status according to the present invention;

FIG 10 is a longitudinal cross-sectional view an alternative embodiment of the pump head and outflow cannula in the expanded status according to the present invention;

FIG 11a is longitudinal cross-sectional of the side view of an alternative embodiment of the pump rotor in the collapsed status according to the present invention;

FIG 11b is longitudinal cross-sectional of the side view of the alternative embodiment shown in FIG 11a of the pump rotor in the expanded status;

FIG 11c is longitudinal cross-sectional of the side view of an alternative embodiment of the pump rotor in the collapsed status;

FIG 11d is longitudinal cross-sectional of the side view of the alternative embodiment shown in FIG 11c of the pump rotor in the expanded status;

FIG 12a is schematic view of an alternative embodiment of the pump rotor in the expanded status according to the present invention;

FIG 12b is longitudinal cross-sectional of the side view of the alternative embodiment shown in FIG 12a of the pump rotor in the collapsed status;

FIG 12c is longitudinal cross-sectional of the side view of an alternative embodiment of the pump rotor in the expanded status;

FIG 12d is a perspective view, partially in section, of the pump rotor shown in FIG 12c rotor in the expanded status;

FIG. 13a is a schematic illustration of the frontal view of an alternative embodiment of the pump head in the expanded status according to the present invention;

FIG. 13b is a is longitudinal cross-sectional of the side view of the alternative embodiment shown in FIG 13a of the pump head in the expanded status;

FIG. 13c is a schematic illustration of the frontal view of the alternative embodiment shown in FIG 13a of the pump head in the expanded status with an outflow cannula in place;

FIG. 13c is a longitudinal cross-sectional of the side view of the alternative embodiment shown in FIG 13a of the pump rotor in the expanded status;

FIG 14a is a perspective view, partially in section, of an alternative embodiment of the pump head in the expanded status according to the present invention;

FIG 14b is a perspective view of the alternative embodiment of the pump head shown in FIG 14 a in the expanded status;

FIG 14b is a perspective view of the alternative embodiment of the pump head shown in FIG 14 a in the collapsed status;

FIG 15 is a schematic illustration of the method of inserting the guide wire into the heart of a patient through a peripheral artery according to the present invention;

FIG 16 is a schematic illustration of the method of inserting the device into the peripheral vessel of a patient and advancing it to the heart according to the present invention; and

FIG. 17 is a perspective view of the cardiac support apparatus disclosed herein being installed through a portal formed in the major blood vessel with the pump head being disposed transvalvularly in a heart chamber.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

Illustrative embodiments of the invention are described below. In the interest of clarity, not all features of an actual implementation are described in this specification. It will of course be appreciated that in the development of any such actual embodiment, numerous implementation-specific decisions must be made to achieve the developers' specific goals, such as compliance with system-related and business-related constraints, which will vary from one implementation to another. Moreover, it will be appreciated that such a development effort might be complex and time-consuming, but would nevertheless be a routine undertaking for those of ordinary skill in the art having the benefit of this disclosure. The systems disclosed herein boast a variety of inventive features and components that warrant patent protection, both individually and in combination.

The blood pump of the present invention may be advantageously introduced into the patient (and onward to the pumping site) while in the first state and thereafter operated (automatically or manually) into the second state for use in pumping blood to augment or replace the pumping capacity of the patient's heart. More specifically, this is accomplished by equipping the blood pump of the present invention with a pump housing with an internally disposed rotor, wherein each of the pump housing and rotor are capable of being expanded from a first state of generally reduced dimension to a second state of generally increased dimension. In this fashion, the blood pump of the present invention may be percutaneously introduced through a much smaller opening than prior art blood pumps without sacrificing the degree to which it can achieve high blood flow rates.

Although the blood pump of the present invention is described herein mainly in terms of an intracardiac application (that is, disposed within the heart), it is to be readily appreciated that it may find application in any number of areas within the patient's circulatory system without departing from the scope of the present invention. The blood pump of the present invention described herein is sized to pump blood at rates comparable to the flow rate of an average healthy heart. That is, it may be sized and configured to discharge blood at volumetric flow rates anywhere in the range of 1 to 8 liters per minute, depending upon the application desired and/or the degree of need for heart assist. For example, for a patient experiencing advanced congestive heart failure, it may be preferable to employ a pump that has an average flow rate of 4.5 to 6 liters per minute. In other patients, particularly those with minimal levels of heart failure or patients that had recovered considerably from heart failure, it may be preferable to employ a flow rate of 3 liters per minute or less.

For clarity, the term "distal" refers to the portion of the device that is inserted first in the patient and "proximal" is the portion that is inserted second. In other words, "distal' refers to furthest end from the using physician while "proximal" is the closest to the using physician.

Referring to FIG 1a, FIG 1b, FIG 2a, and FIG 2b, system 10 of the first embodiment comprises pump 32, outflow cannula 17, outer catheter 45, and drive catheter 12; wherein system 10 is inserted in the patient with pump 32 in a first state of generally reduced dimension shown in FIG 2b and expanded to a second state of generally increased dimension diameter (as shown in FIG 1b) after insertion into the patient.

In accordance with the preferred embodiment of the present invention, and with particular attention being directed to FIG 3a-3d, pump 32 comprises a housing 11and rotor 20. Housing 11comprises outer sheath 22, cannula cage 21, nose cone 39, and housing body 40; wherein outer sheath 22 is preferably made from an elastic material, such as silicone, and partially attached to the outside surface of cannula cage 21. Medially, outer sheath 22 is not attached to cannula cage 21 and shaped to bulge outwardly to form volute 15 when housing 11 internal pressure exceeds external pressure.

In addition, cannula cage 21 is preferably made of multiple nitinol strut 24, which is a super elastic straight annealed material formed substantially of titanium and nickel. Cage 21 may be coated with a biocompatible material, such as titanium oxide, which will reduce the tissue's reaction to the nickel and improve radiopacity. A layer of PTFE may also cover all or portion of cannula cage 21 (i.e. portion of cannula cage 21 not attached to outer sheath 22) to reduce the risk of blood clotting and corrosion. Cannula cage 21 may have radio opaque markers in predetermined positions to aid in deployment and placement of the device. Cannula cage 21 is formed by at least two strut 24 and preferably four to twenty four strut 24.

Cannula cage 21 distal end is attached to the bullet shaped nose cone 39; and cannula cage 21 proximal end is attached to housing body 40. In addition, outer catheter 44 is attached to opposite end of housing body 40 to form outer catheter assembly 45. The interior of housing 11 defines pumping chamber 13 of pump 32. In other words, the inner periphery of housing 11 is the outer periphery of the chamber 13. As is clear from the views of FIGS. 3a and 3b, housing 11 and chamber 13 share a central axis that extends along axis 14 as set forth in FIG. 3a – 3d. Housing 11, and accordingly chamber 13, is provided with a pair of inlet ports, distal inflow port 18 and proximal inflow port 19, along with outlet ports 23. Distal inflow port 18 and proximal inflow port 19 are formed by openings between adjacent cannula strut 24 and outer sheath 22 at the distal and proximal portion of cannula cage 21 and, collectively, define the inlets to chamber 13. In addition, outlet port 23 is formed by the space between adjacent cannula strut 24 in approximately the medial portion of cannula cage 21 wherein outer sheath 22 is not attached to cannula strut 24 (best seen in FIG 4b). Distal inflow port 18 and proximal inflow port 19 are arranged coaxially with chamber 13, that is, along axis 14; with the inlet ports being arranged in oppositely disposed relationship to chamber 13. Outlet port 23 is arranged medially of the inlet ports, and is, as indicated, disposed generally transversely of axis 14. Since pump 32 is generally a centrifugal pump, wherein blood inflow through distal inflow port 18 and proximal inflow port 19 along axis 14 and exit at an angle preferably between 45 and 90 degrees (exit angle shown is 90 degree in all figures is used for example only) to axis 14 through outlet port 23. In addition, housing 11 comprises volute 15, wherein outer sheath 22 and strut 24 are not attached, and which forms a circumferentially expanding area of housing 11 intended to collect blood from outlet port 23 and channel it toward outflow cannula 17.

In accordance with the preferred embodiment of the present invention, and with particular attention being directed to FIGS. 3a, 3b, 4a and 4b of the drawings, rotor 20 is disposed within pumping chamber 13 and has a tubular shape, when it is collapsed for insertion (as shown in FIG 3b) and takes a spherical shape when deployed for operation (as shown in FIG 4b). Rotor 20 comprises multiple blade 26 formed by outer rotor sheath 27 and rotor cage 28, wherein outer rotor sheath 27 is preferably made from an elastic material, such as silicone, and attached to the outside surface of rotor cage 28. In addition, rotor cage 28 is preferably made of multiple nitinol rotor strut 31, which is a super elastic straight annealed material formed substantially of titanium and nickel. Rotor cage 28 is formed by at least three rotor strut 31 and preferably 4-12 rotor strut 31. Cannula cage 21, cannula strut 21, outer sheath 22 have some similarities to rotor cage 28, rotor strut 31, and rotor sheath 27 respectively in shape, material, and manufacturing method, with the material of construction being either similar or identical. A suitable biocompatible and non-thrombogenic coating may be applied in order to enhance the biocompatibility of the structure.

Rotor strut 31are mounted on rotor mandrel 35 with rotor strut distal end 36 is attached to rotor mandrel 35 while rotor strut proximal end 37 could freely slide over rotor mandrel 35. Both rotor strut ends, rotor strut distal end 36 and rotor strut proximal end 37, are joined, bonded, or welded together to form a tubular shape with an inside diameter that matches closely the outside diameter of rotor mandrel 35. Alternatively, rotor strut 31, rotor strut distal end 36, and rotor strut proximal end 37 could be manufactured from a nitinol tube; wherein material is removed from the tube wall to create adjacent strut 31 while keeping both tube ends intact to form rotor strut distal end 36 or rotor strut proximal end 37. Heating the cut tube to temperatures that causes permanent material deformation while deforming the cut tube to the desired shape will result in a rotor skeleton similar to the one described above. Shaping nitinol is, of course, well known in the art. Normally, rotor strut 31, collectively, form a spherically shaped rotor. In case an inwardly radial force is exerted on rotor strut 31, rotor strut proximal end 37 will slide apart from rotor distal end 36 over rotor mandrel 35 and cause rotor strut 31 to collapse and assume a flat, or collectively a tubular, shape that is smaller in diameter. In other words, rotor 20 is naturally spherical in shape, but pulling its ends apart transforms its shape into a tubular shape. In other words, when cannula cage 21 is

expanded, as described above, rotor 20 regain its natural expanded shape. Obviously, when cannula cage 21 is collapsed it forces rotor 21 to collapse to its tubular shape.

Referring to FIG 5a and 5b, rotor mandrel 35 comprises at least two bearing surfaces, distal bearing 41 and proximal bearing 42, which are designed to allow the free and smooth rotation of mandrel 35 at high speed with minimum wear and heat generation. Both bearings, distal bearing 41 and proximal bearing 42, could be of the roller bearing type (as shown in FIG 5a and FIG 5b) and could be either bonded or welded to rotor mandrel 35, nose cone 39, and housing body 40. Mandrel 35 is only bonded (or welded) to distal bearing 41 but not to proximal bearing 42; therefore mandrel 35 could freely slide inside proximal bearing 42 to allow the expansion and collapse of pump 32, as will be described in more detail later. Mandrel 35 comprises blood seal 30 that mate the seal face 25 of housing body 40 during device operation that serves to keep blood outside the proximal bearing 42 area and the device interior. Similarly, nose cone 39 is fitted with a lip seal 38, which is a rubber ring designed to close against mandrel 35 and nose cone 39 to keep blood outside distal bearing 41 area and the device interior. Lip and shaft seals for such applications are, of course, well known in the art. In addition, rotor mandrel 35 comprises a central lumen 47 that traverses the entire length of the length of rotor mandrel 35 and form part of a continuous central lumen through the entire length of the catheter that allow the passage of a guide wire. Central lumen 47 is closely aligned with axis 14.

Rotor 20 has an axial length along the axis of rotation as being generally equal to the axial length of pumping chamber 13 between the inflow ports 18 and 19. The transverse diameter of the rotor 20 is defined along a medial plane, as along medial line A—A, and with the configuration of the rotor 20 and pumping chamber 13 providing a clearance between the outer surface of the rotor and the inner surface of the pumping chamber as illustrated in greater detail in FIG. 4b. Generally speaking, the clearance between the outside periphery of rotor 20 and the inside periphery pumping chamber 13 is constant except in volute 15 area; wherein the clearance, as indicated at A--A is such that the clearance increases axially and radially to create a typical volute design. With these considerations in mind, the clearance between the inner surface of the pumping chamber 13 and the periphery of the rotor 20 preferably ranges between about 0.005 inch up to

about 0.08 inch, with a narrower range of between about 0.01 inch to 0.04 inch being generally preferred. Generally, a clearance of about 0.015 is preferred.

In accordance with the preferred embodiment of the present invention, outflow cannula 17, is made from a soft highly flexible rubber (such as silicone) or plastic that could be manufactured in very thin walls to create a tubular structure. Outflow cannula 17 is collapsed and wrapped around pump 32 and outer catheter 44 to form a low profile during insertion into the patient. Outflow cannula, outer sheath 22, and volute 15 could be made from the same material and could form a unitary component of system 10; or, alternatively, outflow cannula 17 and volute 15 could form a unitary component of system 10 as shown in FIG 6. In accordance with the preferred embodiment of the present invention, tip 34 of outflow cannula 17 is necked to reduce its diameter in order to increase the pressure within outflow cannula 17 and to eliminate the possibility of kinking or collapsing due to external forces exerted on outflow cannula 17 outer diameter. It is possible to reinforce outflow cannula 17 with small diameter wire or plastic filaments in order to give it more rigidity and structural strength. In case wire is used for reinforcement, nitinol or similar material is preferred since outflow cannula 17 is deformed at the time of its insertion into the patient and is required to regain its tubular shape after insertion.

In accordance with the preferred embodiment of the present invention, outer catheter 45 comprises outer catheter 44, which is preferably made from extruded plastic that is biocompatible and anti-thrombotic on the exterior while possessing a high resistance to wear on interior surface. It is possible to use a co-extruded catheter to create a single catheter that have these varied requirement, for example, the outer extrusion could be a urethane that is known for its biocompatability while the inner extrusion is a Teflon based plastic, which has a high resistance to wear. The high wear resistance of the interior extrusion is required since drive catheter 12 will rotate at a high rotational speed to generate the flow required. Co-extruded catheter for such applications is, of course, well known in the art.

In accordance with the preferred embodiment of the present invention, drive catheter 12 distal end is attached to rotor mandrel 35 proximal end while its proximal end is attached to an electric motor 57 placed outside the patients body as shown in FIG 16.

Drive catheter 12 is made from a metallic or non-metallic material that is capable of transmitting the rotation of an electric motor 57, located outside the patient body, to rotor 20. Typically, helical winding of several metallic wire has been used in similar devices such as the Hemopump. In addition, drive catheter 12 is used to expand or collapse pump 32 from a small insertion diameter to a larger operational diameter. Pulling the distal end of pump 32 while holding its proximal end fixed (i.e. shortening pump 32) expands system 10. In the preferred embodiment of the present invention, drive catheter 12 is indirectly attached to nose cone 39 and could freely slide inside outer catheter assembly 45; therefore pulling on drive catheter 12 while keeping outer catheter 45 fixed will cause pump 32 to expand radially (as shown in FIG 1b) and for blood seal 30 to close against seal face 25 (as shown in FIG 5a). After pump 32 is energized, the higher pressure inside pump 32 causes outflow cannula 17 to fully inflate.

In accordance with an alternative embodiment of the present invention, and with particular attention being directed to FIG 7a and 7b, an alternative rotor design that could be used with system 10 could comprise a hub 50 with multiple hinged blade 51 attached to hub 50 by hinge pin 52, which permit hinged blade 51 free rotation around hinge pin 52. In other words, hub 50 rotation in one direction causes hinged blade 51 to either swing around hinge pin 52 to an "open" or "close" position. In the "open" position hinged blade 51 could act as an impeller blade and cause a lift or centrifugal force to cause the movement of fluid in the proximity of the rotor to move against pressure gradient and generate a net fluid flow in one direction. Stop pin 53 on hub 50 is located in the swinging path of hinged blade 51 to limit the degree hinged blade 51 could swing out. Hub 50 could comprise at least 2 hinged blade 51 and preferably 3 to 8 hinged blades. In addition, hinged blade 51 could be attached to either surface of hub 50; therefore allowing twice the maximum number of hinged blades that could be fitted on one surface of hub 50. In addition, hinged blade 51 could be shaped in a fashion to generate a lift force along axis 14, wherein rotor 20 would function similarly to an axial rotor, wherein blood is energized to move axially along axis 14 rather than obliquely to axis 14 as in a centrifugal pump.

In accordance with an alternative embodiment of the present invention, and with particular attention being directed to FIG 8a- 8d, an alternative outflow cannula could used, wherein the cannula is a tubular structure that is attached to cannula strut 24 to

replace outer sheath 22 and volute 15 is eliminated. According to this embodiment, pump 32 retains one inflow port, the distal inflow 18 while the proximal port becomes the axial outflow port 61 of pump 32, wherein blood enter distal inflow port 18 and exit through axial outflow port 61 instead of outlet port 23 into axial outflow cannula 62, which is made of thin flexible material such as silicone.

In accordance with the alternative embodiment of the present invention shown in FIG 8a – 8d, and FIG 9, axial rotor 65 is similar to rotor 20 with the exception of the axial rotor strut 68 deploy in a helical shape (as shown in FIG 9), when expanded, rather than arc shape as was described previously in relation to rotor 20. In other words, axial rotor strut 68 expand in a plane oblique to axis 14, main rotation axis, versus rotor strut 31 of rotor 20 deploy in a plane that is relatively parallel to axis 14. In this case, axial rotor 65 has a generally helical shape and therefore its rotation causes blood to move in an axial path parallel to axis 14. An alternative axial rotor with capability to collapse during insertion and deploy to a larger diameter, such as the rotor shown in FIG 7, could be used in place of rotor 65 to cause blood movement in an axial path in the present embodiment.

Now referring to FIG 10, a secondary expandable element 64 that comprises a cage, similar to cannula cage 21 and rotor cage 28, is preferably made of multiple nitinol strut that will assist in maintaining axial outflow cannula 62 open during use. Secondary expandable element 64 may be coated with a biocompatible material, such as titanium oxide, which will reduce the tissue's reaction to the nickel and improve radiopacity. A layer of PTFE may also cover secondary expandable element 64 to reduce the risk of blood clotting and corrosion. Secondary expandable element 64 is formed by at least two struts and preferably four to eight struts. Multiple secondary expandable element 64 could be included along the length of axial outflow cannula 62 to support its entire length. The expansion or collapse of secondary expandable element 64 is similar to expansion or collapse of cannula cage 21 and rotor cage 28 (not shown) by an axial translation of the distal end toward the proximal end while keeping the proximal end fixed in place. In addition, secondary expandable element 64 could be shaped to normally be in the expanded position; therefore, during insertion expandable element 64 collapse automatically and then re-expand when in a larger portion of the vascular system. In accordance with alternative embodiment of the present invention, the rotor design could be modified while keeping the rest of system 10 generally as described above.

In accordance with another alternative embodiment of the present invention, and with particular attention to FIG 11a and 11b, a rotor shape is attained by having sleeve 67, which is made of a thin flexible material such as silicone, cover a preformed nitinol wire 65, wherein preformed nitinol wire 65 if stretched will take a low profile and if relaxed will take a spiral shape and force sleeve 67 into a helical shape (as shown in FIG 11b).

In accordance with another alternative embodiment of the present invention, and with particular attention to FIG 11c and 11d, a rotor shape is attained by having sleeve 67, which is made of a thin flexible material such as silicone, cover a straight nitinol wire 63, wherein straight nitinol wire 63 will normally have a straight shape (as shown in FIG 11c) with a low profile and when sleeve distal ring 59 is rotated relative to rotor proximal end 58 by means of rotation shaft 57 the sleeve is forced into a helical shape as shown in FIG 11d. Rotation shaft 57 could be manually rotated to cause sleeve 67 deformation, or it could be part of the rotation induced by the electric motor 57 used to rotate the rotor to induce blood flow. In other word, the rotor is deployed into its helical shape as the device is energized to pump blood; therefore the rotor deploy into its helical shape upon the first few revolutions of the electric motor 57.

In accordance with another alternative embodiment of the present invention, and with particular attention to FIG 12a- 12d, the rotor could be made from flexible material 66 covered by sleeve 67 that both could be folded backward (as shown in FIG 12B) to create a low profile during insertion into the patient. During placement of the device, the rotor is in the folded condition shown in FIG. 12b once within or past the insertion site flexible material is allowed to flex back to its initial shape and increase the rotor diameter and form a helix as shown in FIG 12a.

The variant of FIG. 12c and 12d differs from that of FIGS. 12a and 12b only in that the sleeve 67 is supported by a balloon element 69 that is fabricated of a single layer of elastomeric material. In other words, it does not have a nonelastic inner layer, such as the flexible material 66. The sleeve 67 is molded to have a predetermined set so that it inflates to a helical configuration, while collapsing to a contracted configuration with low profile upon deflation. Balloon element 69 is inflated through inflation orifice 72, which

is in communication with inflation lumen 71 by means of a syringe (not shown) as is typical in ballooned catheters.

In accordance with another alternative embodiment of the present invention, and with particular attention to FIG 13a –13d, hinged pump 100 comprises hinged housing 90 and hinged rotor 80; wherein housing 90 comprise multiple hinged element 92 that are attached at one of their ends by means of pivot pin 91 and the other ends are either attached to hinged nose cone 93 or hinged body 94 by means of two additional pivot pin 91. Hinged rotor 80 comprised multiple rotor hinged element 82 that are attached at one of their ends by means of rotor pivot pin 81 and the other ends are either attached to hinged rotor cone 84 or hinged rotor body 85 by means of two additional pivot pin 81. Hinged housing 90 and hinged rotor 80 could increase in diameter by pulling on hinge rod 87 to bring hinged nose cone 93 closer to hinged body 94. Distal hinged bearing 88 and proximal hinged bearing 89 allow the free rotation of hinged rotor 80 inside hinged housing 90 and hinged nose cone 93. A flexible sheath 95 is attached to the exterior surface of hinged housing 90 to form the distal end of an outflow cannula (not shown) as described in previous sections. In addition, a similar sheath could cover hinged rotor 80 to form a rotor similar in function to rotor 20, which was detailed earlier. System 100 could be modified to function as either an axial or centrifugal pump depending on the outflow cannula design, as well as, the rotor design.

In accordance with another alternative embodiment of the present invention, and with particular attention to FIG 14a –14c, disc pump 120 comprises a collapsible housing 101 and disc rotor 102, wherein collapsible housing 101 is similar to previously described housing in having a collapsible frame 103 covered by an external sheath 104 that form the distal part of a tubular cannula 105. External sheath 104 partially covers collapsible frame 103 distal end, wherein the section not covered forms disc pump inflow 108 wherein blood enter disc pump 120. Disc rotor 102 comprises at least one disc 106 that is attached to rotation mandrel 107. Pulling on rotation mandrel 107 to cause the distal end of disc pump 120 to move closer to its proximal end causes collapsible housing 101 to enlarge in diameter; therefore allowing disc 106 to expand to a larger diameter. Rotation of rotation mandrel 107 causes disc 106 to deploy to its fullest diameter and to impart a centrifugal force on the fluid in the neighborhood of disc 106 and to move outwardly toward collection area 109 before flowing under pressure into tubular cannula 105.

The method for implanting system 10 will now be described. The method described will detail the placement of system 10 in the left ventricle with outflow cannula 17 placed across the aortic valve 3 into the aorta 6 wherein pump 32 is removing blood from the left ventricle 9 to be discharged through cannula 17 into the aorta 6. It is to be readily appreciated that this description is set forth by way of example only. That is, the teachings of the method described below could be employed to place system 10 in any heart chamber to pump blood from different parts of the heart to other parts of the circulatory system. Any such modifications may be made without departing from the spirit and scope of the present invention.

The first aspect of the method of the present invention involves introducing the system 10 into the desired location within the heart. FIGS.15, 16, and 17 illustrate system 10 in the left ventricle. Under Fluoroscopic guidance guide wire 74 is first inserted into the femoral artery using a conventional Seldinger technique, which involves threading a guide-wire through a Seldinger needle. Guide wire 74 is long enough to allow a substantial length to extend out of the body at the groin for manipulation even when the distal ends of the guide wire 74 is positioned in the heart. The fluoroscopic display of guide wire 74 provides confirmation of proper positioning across the aortic valve 3 into the left ventricle 9. At user discretion, different catheters and guide wires might be employed prior to placing guide wire 74 across the aortic valve 3. Guide wire 74 is a small diameter metallic guide wire with a diameter ranging between 0.008 to 0.018 inch and preferably 0.012 inch. Guide wire 74 tip is typically made form a fine spring like structure specifically designed to be atraumatic to tissue that get in contact with guide wire 74 tip during guide wire 74 insertion. Guide wire and catheter usage for such applications is, of course, well known in the art.

Once guide wire 74 is in the left ventricle, Guide wire 74 assists in guiding system 10 to the left ventricle 9 of the heart under fluoroscopic guidance. Once guide wire 74 is in the left ventricle, the proximal end of guide wire 74 is inserted through central lumen 47 of system 10. Next, system 10 is collapsed to its smallest diameter by a rotating profile knob 46, which is a typical mechanical design that could cause cannula cage 21 and rotor 20 to simultaneously expand or collapse, as described above. System 10 is then advanced in its collapsed form over the wire to the left ventricle. The

fluoroscopic display provides an indication of the actual location of system 10. As an option, a radio-opaque dye may be injected through central lumen of outer catheter 44 to discharge through blood seal 30 to further confirm the location of system 10.

When the system 10 is properly positioned, guide wire 74 is retracted from the left ventricle into central lumen 47 before starting system 10 operation. Typically, central lumen 47 is filled with a high viscosity lubricating material, such as glycerin gel, that keep blood from entering central lumen 47 distal end or air entering central lumen 47 proximal end. Optionally, lubricating fluid with relatively moderate viscosity, such 40% dextrose, could be injected into the system through the central lumen of outer catheter lumen 44 to reduce possible wear between the rotating internal drive cable 48 the inner diameter of outer catheter 44. In addition, this lubricating fluid could be used to wash blood seal 30, seal face 25, and lip seal 38 from any blood that might tend to stagnate in the seal area. This lubricating system is well described in prior art such as the Hemopump and is well known in the art.

While this invention has been described in terms of a best mode for achieving this invention's objectives, it will be appreciated by those skilled in the art that variations may be accomplished in view of these teachings without deviating from the spirit or scope of the present invention. As can be envisioned by one of skill in the art, many different combinations of the above may be used and accordingly the present invention is not limited by the scope of the appended claims.